DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

MicroArray Quality Control Project Meeting on MicroArray Quality Control; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "MicroArray Quality Control (MAQC) Project Meeting on MicroArray Quality Control." The focus of the 2-day meeting will be to review the datasets generated by the MAQC study.

Date and Time: The meeting will be held on Thursday, December 1, 2005, from 8 a.m. to 5 p.m. and Friday, December 2, 2005, from 8 a.m. to 2 p.m.

Location: The meeting will be held at the Crowne Plaza Cabana Portofino Room on December 1, 2005, and the St. Tropez Room on December 2, 2005, 4290 El Camino Real, Palo Alto, CA 94306, 650–857–0787, FAX: 650–496–1939, Web site: *http://www.cppaloalto.crowneplaza.com/*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Contact: Leming Shi, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870–543–7387, FAX: 870–543–7686, e-mail: *leming.shi@fda.hhs.gov*.

Registration: There will be no registration fee for attending the meeting. However, interested parties should send registration information (including name, title, firm name, address, telephone, and fax number), and written

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material and requests to make oral presentations, to the contact person (see *Contact*) at least 15 days in advance of the meeting. Participants are responsible for their own costs of travel, lodging, and meals.

FDA welcomes the attendance of the public at this meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jeannette Coleman at 870–543–7087, e-mail: *jeanette.coleman@fda.hhs.gov*, at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION: FDA's critical path initiative (*http://www.fda.gov/oc/initiatives/criticalpath/*) identifies pharmacogenomics as a key opportunity in advancing medical product development and personalized medicine. FDA issued the "Guidance for Industry: Pharmacogenomic Data Submissions" (*http://www.fda.gov/cder/guidance/6400fnl.pdf*) to facilitate scientific progress in the field of pharmacogenomics and to facilitate the use of pharmacogenomic data in drug development and medical diagnostics. A microarray is a tool for analyzing gene expression that consists of a small membrane or glass slide containing samples of many genes arranged in a regular pattern. Microarrays represent a core technology in pharmacogenomics; however, before this technology can successfully and reliably be applied in clinical practice and regulatory decisionmaking, standards and quality measures need to be developed.

The MAQC project involves six FDA centers, major providers of microarray platforms and ribonucleic acid (RNA) samples, government agencies, academic laboratories, and other stakeholders. The MAQC project aims to evaluate quality control metrics and thresholds for objectively assessing the performance achievable by various microarray platforms, and

evaluating the advantages and disadvantages of various data analysis methods. Two RNA samples will be selected for three species (i.e., human, rat, and mouse), and differential gene expression levels between the two samples will be calibrated with microarrays and other technologies (e.g., quantitative real time-polymerase chain reaction (qRT–PCR)). The resulting microarray datasets will be used for assessing the precision and crossplatform/laboratory comparability of microarrays, and the qRT–PCR datasets will enable evaluation of the nature and magnitude of any systematic biases that may exist between microarrays and qRT–PCR. The availability of the calibrated RNA samples and the resulting microarray and qRT–PCR datasets, which will be made readily accessible to the microarray community, will allow individual laboratories to identify and correct procedural failures more easily. The MAQC project will help improve the microarray technology and foster its proper applications in discovery, development and review of FDA-regulated products. For more information about the MAQC project, please visit *http://www.fda.gov/nctr/science/centers/toxicoinformatics/maqc/*.

At the public meeting, each participating platform provider will give a 15-minute presentation to summarize the datasets generated by its test sites and to describe its analysis results. Each analysis site will also give a 15-minute presentation on its analysis results. Other interested parties may present data, information, or views, orally or in writing, on issues related to microarray quality control and data analysis. Those desiring to make formal oral

presentations should notify the contact person (see *Contact*) before November 4, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present with an indication of the approximate time requested to make the presentation.

Dated: OCT 17 2005
October 17, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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